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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,645	01/10/2002	Anthony L. Almada	374582000120	9302

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/17/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,645

Applicant(s)

Almada

Examiner

Christopher Tate

Art Unit

1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 10, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-13, and 15-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-13, and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 5 1/2 6) ☐ Other:

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DETAILED ACTION

Claims 1-4, 9-13, and 15-22 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 18 are rendered vague and indefinite by the phrase "*Citrus aurantium* or other natural source of synephrine". There is insufficient antecedent basis for the limitation "synephrine" within this phrase, because *Citrus aurantium* is not instantly defined as containing synephrine. It is suggested that this phrase be expanded to recite --an extract of *Citrus aurantium* containing synephrine therein, or other natural source of synephrine-- (or similar phraseology).

Claim 10 recites the limitation "the sympathomimetic agent" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Although the preamble recites "a sympathomimetic agent", this limitation should also be positively recited within the body of the independent claim. Accordingly, it is suggested that "the sympathomimetic agent" in lines 2-3 be amended so as to recite --a sympathomimetic agent--.

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All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by each of the Product Alert abstracts of 12 Dec 1992 and 22 July 1996, with evidence provided by Myers et al. (US 2002/0127189).

Each of the cited Product Alert Bulletins disclose commercial orally ingestible pharmaceutical products comprising saw palmetto (or extract thereof) in combination with ma huang (which is admittedly and well recognized in the art to inherently contain the various sympathomimetic compounds instantly claimed) - see abstracts. In addition, please note that, as evidenced by Myers et al. (see, e.g., page 1, paragr 0014) - ma huang (aka *Ephedra*) naturally and inherently contains ephedrine alkaloids including norephedrine (which, as readily admitted by applicant, is also known as phenylpropanolamine - see, e.g., page 1, line 25 of the instant specification) therein. The disclosed products further comprise ingredients which are well recognized in the art to inherently contain caffeine - e.g., cola nut and green tea, respectively.

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Therefore, each of the cited references is deemed to anticipate the instant claims above.

As discussed in the last Office action of parent application 09/672,109, the method of claims 10-13 and 15-19 are free of the art. Although the prior art teaches the combinational use of the claimed ingredients, there is no reasonable suggestion in the prior art of record to administer *Serenoa repens* in combination or prior to administering a sympathomimetic agent, such as those found in *Ephedra* (and/or admixed with caffeine), in an amount effective to alleviate (reduce) the side effects of the sympathomimetic agent to a subject in need thereof, such as instantly disclosed (and claimed). In addition, the teachings of Locke (US 6,200,573 - which was filed after the filing date of the instantly claimed priority document) indicate the synergistic combinational use of an α -adrenergic antagonist and saw palmetto extract (for treating symptoms of benign prostate hyperplasia) which reasonably indicates that both of these ingredients act synergistically as alpha-adrenergic antagonists vs. the instant method claims which are drawn to administering saw palmetto (or extract thereof) to counteract the side effects of an alpha-adrenergic (sympathomimetic) agent such as ephedrine and/or other art-recognized alpha-adrenergic compounds obtained from *Ephedra*.

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Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654